DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

December 26, 2006

Ref: **2007-DAL-WL-3**

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Ms. Terri A. Hadley, President
Lee Laboratories, Inc.
408 Fairview Avenue
Ponca City, Oklahoma 74601-1922

Dear Ms. Hadley:

During an inspection of your firm located at the above referenced address on September 25 through 27, 2006, the United States Food and Drug Administration (FDA) determined that your firm manufactures extraoral orthodontic headgear (e.g. the High Pull, Straight Pull, Low Pull Cervical, Variable Pull, Cervical Neck Strap, High Pull Double Hook, and Safety Modified High Pull) intended to exert pressure on the teeth from outside the mouth Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 321(h)), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. Your devices are also misbranded under section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), because your firm failed to establish and maintain written medical device reporting (MDR) procedures, as required by section 519 of the Act, 21 U.S.C. § 360i, and the MDR regulation, 21 CFR Part 803.

We received a response from your Office Manager, dated October 4, 2006, responding to our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, which was issued to her (copy enclosed) on September 27, 2006. Your Office Manager responded that your firm chose not to correct the current inspectional observations and that your firm would close its business in 60 days. The FDA has not received a direct response from you to confirm your intention of closing your firm as you were not present at the conclusion of the inspection. The current inspection documented that your firm made very few corrections and that many of the items listed on the current FDA 483 were repeat observations from the previous inspection of August 2004. Your devices were manufactured and released for distribution in the absence of adequate quality system procedures. You are advised that your firm's continued distribution of the adulterated and misbranded devices is prohibited under section 301 of the Act, 21 U.S.C. § 331.

These violations include, but are not limited to, the following:

1. Failure of the management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization, as required by 21 CFR § 820.20. FDA-483 Item 1 through 21. For example:

   a. The previous August 2004 inspection involved the issuance of a 31-item FDA-483 to your firm. Your firm made inadequate corrections as many of the current inspectional observations were repeat observations from the previous inspection. During the current inspection, you verbally expressed to the investigator that you and your co-owners were not interested in learning and understanding the FDA's quality system requirements.

   b. You have not established and maintained a quality plan, quality audit procedures, and conducted such quality audits. These are repeat observations from the previous August 2004 inspection.

   c. You failed to provide adequate resources to ensure that your firm's Office Manager obtains the necessary training in order for her to understand and implement the quality system requirements or seeks assistance from a qualified quality system consultant to provide training and/or develop adequate quality system procedures.

2. Failure to establish and maintain adequate complaint handling procedures for receiving, reviewing, and evaluating complaints by a formally designated unit and to ensure that all the requirements of 21 CFR § 820.198(a) through (e) are met. FDA-483 Item 8, a repeat observation from the previous August 2004 inspection. For example:

   a. Your Office Manager stated that your firm received customer complaints but has not formally documented and investigated them. Your Office Manager further stated that some time ago your firm received a complaint from a dentist alleging that one of his patients was having allergic reactions to the J-Hooks and had developed a rash on the face. This information was not documented and investigated to determine whether the incident is reportable to FDA.

   b. Your firm has a complaint form "Standard Form For Complaints," but this form does not document all the requirements for handling complaints, including reviewing complaints for MDR reportability.

3. Failure to establish and maintain adequate procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria prior to releasing the devices for distribution, as required by 21 CFR § 820.80(d), and failure to review acceptance records for adequacy prior to releasing the devices, as required by 21 CFR § 820.80(e). FDA-483 Item 5, a repeat observation from the previous August 2004 inspection. For example:

   a. Your firm's procedure "Final Acceptance Checklist" does not document any specific device specifications, how the devices are to be inspected or tested for acceptance or rejection, and specific acceptance criteria (e.g. types of defects and the nature of defects).

   b. Your firm has not assigned and documented a responsible person for reviewing and approving device acceptance records for adequacy prior to releasing the devices for distribution. For example, your firm reviewed Work Order # 2271 for acceptance activities on 9/21/06 after the devices were commercially distributed on 9/11/06.

4. Failure to establish and maintain procedures for acceptance or rejection of incoming product, and for documenting the results of acceptance or rejection, as required by 21 CFR § 820.80(b). FDA-483 Item 6, a repeat observation from the previous August 2004 inspection. For example:

a. Your firm's procedure "Acceptance Sheet for Receiving Goods" does not document any specific incoming component specifications, how the components are to be verified, inspected, or tested for acceptance or rejection, and the quantity rejected or accepted. This form states to inspect incoming components for "Good," "Fair," and "Poor" conditions but does not define specific acceptance criteria for these three conditions.

b. Your firm has not always recorded the results of acceptance activities for every lot or shipment of components received. See Invoices, dated 5/10/06 and 5/25/06 for two shipments of metal wires received to manufacture the J-Hooks.

5. Failure to establish and maintain procedures to control product that does not conform to specified requirements and to address the identification, documentation, evaluation, segregation, and disposition of nonconforming product, as required by 21 CFR § 820.90(a). FDA-483 Item 7, a repeat observation from the previous August 2004 inspection. For example:

   Your firm has not established and maintained procedures for identifying, segregating, and dispositioning rejected components or finished devices. Your Office Manager showed the investigator some rolls of a material used to manufacture the straps of the headgears that were wound backwards. These rolls were not identified and documented as being rejected or quarantined. Your Office Manager said that your firm was not to use the rejected rolls but did not document its disposition.

6. Failure to establish and maintain procedures for rework, including retesting and reevaluation of the nonconforming product after rework, to ensure that the product meets its current specifications and its rework activities are documented in the device history record, as required by 21 CFR 820.90(b)(2). FDA-483 Item 7, a repeat observation from the previous August 2004 inspection. For example:

   Your firm has not established and maintained any rework procedures. Your Office Manager stated that your firm had reworked some of the headgears such as removing their defective staples and replacing them with new staples. Rework activities and inspection results were not documented. Your firm also has not documented how many times a nonconforming product can be reworked.

7. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR § 820.50(a). FDA-483 Item 9 and 10, repeat observations from the previous August 2004 inspection. For example:

   a. Your firm has not documented and approved written specifications for device components purchased (e.g. metal wires, staples, straps, pads, plastic, boot hooks, and elastic bands).

   b. You firm sent the metal wires to a contract manufacturer to make the J-Hooks, a component of the headgears. Your firm has not defined any quality requirements this contract manufacturer must meet and/or how your firm inspects the J-Hooks for acceptance or rejection.

8. Failure to maintain device master records (DMR's) to include or refer to the location of device specifications, production process specifications, quality assurance procedures, and packaging and labeling specifications, and to ensure that each DMR is prepared and approved in accordance with 21 CFR § 820.40, as required by 21 CFR § 820.181. FDA-483 Item 11, 12, and 20, repeat observations from the previous August 2004 inspection. For example:

   a. Your firm has not defined and documented specifications for components (e.g. metal wires, staples, straps, pads, plastic, boot hooks, and elastic bands) used to manufacture the referenced devices.

   b. Your drawings used to assemble the headgear devices do not document any legends, dimensional specifications, components and their materials, and labels affixed to the devices.

   c. Your firm has a chart that showed handwritten changes to the device sizes. These changes were not reviewed and approved by the responsible individual(s). Your Office Manager said that your firm had changed the type of the staples because of a problem with rusting. A description of the change and the materials of the staples before and after the change were not documented.

9. Failure to establish and maintain procedures to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record, as required by 21 CFR § 820.184. FDA-483 Item 16. For example:

a. Your firm's Final Acceptance Checklist does not document specific instructions describing how each type of the referenced devices is inspected or tested for conformance with their respective device drawing.

b. Your firm does not document the dates of manufacturing for the devices in their record "Master Control for Individual Order."

10. Failure to establish and maintain procedures to control labeling activities, as required by 21 CFR § 820.120. FDA-483 Item 18, a repeat observation from the previous August 2004 inspection. For example:

a. Your device drawings do not show the location of the device labels, and your firm has not documented which label is used for each type of headgear.

c. Your firm has no procedures for examining device labeling for accuracy.

d. Your firm [redacted] on each headgear to identify the date of manufacture. There is no procedure describing how to determine the date of manufacture from reading the orientation of the [redacted]

11. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR § 820.100(a)(1) through (a)(7), and to include documentation of the results of corrective and preventive action activities, as required by 21 CFR § 820.100(b). FDA-483 Item 13. For example:

Your firm does not have any written procedures for implementing and documenting corrective and preventive action.

12. Failure to establish and maintain procedures for the identification, documentation, validation or verification, review, and approval of design changes before their implementation, as required by 21 CFR § 820.30(i). FDA-483 Item 20, a repeat observation from the previous August 2004 inspection. For example:

Your firm does not have any written procedures for reviewing, documenting, verifying or validating, and approving design changes to your headgear.

Your devices are also misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed to furnish any material or information respecting the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 -- Medical Device Reporting (MDR) regulation. For example, your firm failed to establish and maintain adequate written MDR procedures, as required by 21 CFR § 803.17, and maintain documentation and record keeping requirements for MDR event files, as required by 21 CFR § 803.18. FDA-483 Item 21.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Also, federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the QS regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective action you have taken. If your planned corrections will occur over time, please include a timetable for implementation of these corrections. If the corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Thao Ta, Compliance Officer, DAL-DO, Food and Drug Administration, HFR-SW140, 4040 N. Central Expressway, Suite 300, Dallas, TX 75240. If you have any questions about the contents of this letter, please contact Mr. Ta at 214-253-5217.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Form FDA-483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the

causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely,

for Sylvia G. Lyles
Michael A. Chappell
Dallas District Director

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